FEB 2 8 2002

510(k) Summary

K013819

I. General Information on Submitter

Name:	Sierra Diagnostics, L.L.C.
Address:	21109 Longeway #C Sonora, CA 95370
Telephone:	(209) 536-0886
Fax:	(209) 536-0853
Contact Person:	Tony Baker
Date Prepared:	October __, 2001

II. General Information on Device

Name:	Sierra Diagnostics L.L.C. Urine Collection, Preservation and Transport System
Classification Name:	Accessory to Neisseria spp. and Chlamydia serological reagents

III. Predicate Device

The standard urine collection cup used to collect specimens for testing with the Abbott LCx® *Neisseria gonorrhoeae* and *Chlamydia trachomatis* assays and referenced in the package inserts for the LCx® devices (See 510(k) Nos. K935833 (*Neisseria gonorrhoeae*) and K934622 (*Chlamydia trachomatis*)).

IV. Description of Device

The device is comprised of a urine collection cup containing of a nucleic acid chemical preservative. The device allows urine specimens for LCx® gonococcal or chlamydial testing to be preserved for up to 6 days at temperatures not to exceed 60°C. Inert indicator beads are included in the urine cup as an indicator that a preservative is present in the sample.

V. Intended Use

The Sierra Diagnostics L.L.C. Urine Collection, Preservation and Transport System is intended for use in the collection, preservation, and transportation of urine specimens at temperatures not exceeding 60°C for testing with the Abbott LCx® *Neisseria gonorrhoeae* and *Chlamydia trachomatis* assays.

VI. Technological Characteristics of Device Compared to Predicate Device

The Sierra Urine Collection, Preservation, and Transport System and the predicate device share the same technological characteristics with the exception of the method of preservation. The predicate device employs a temperature preservation method while the Sierra device uses chemical preservation.

VII. Summary of Performance Data

The effectiveness of the Sierra Urine Collection, Preservation, and Transport System was established by the comparative testing of fresh and preserved urine spiked with gonococcal and chlamydial DNA. LCx® testing of samples that were preserved through refrigeration for 24 hours were compared with results for specimens preserved with the Sierra device and tested after being held for 144 hrs. at 60°C. There was a 100% correlation between the refrigerated and preserved samples.

Effectiveness was further established by a multi-site clinical study. The results of this study demonstrated that the device effectively preserved gonococcal and chlamydial nucleic acid targets in urine specimens from symptomatic and asymptomatic males and females.

The effective preservative concentration range and effect on LCx® sensitivity was established by a study using urine specimens spiked with less than 10 cfu of 10 different gonococcal serovars. Results from this test proved that Sierra's device effectively preserved nucleic acid targets down to the LCx® level of detection with a preservative to urine ratio ranging from 1:10 to 1:15.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Sierra Diagnostics, L.L.C.
c/o Donald R. Stone, Esq.
Kirkpatrick and Lockhart, LLP
1800 Massachusetts Avenue, NW
Suite 200
Washington, DC 20036-1221

Re: k013819
Trade/Device Name: Sierra Diagnostics L.L.C. Urine Collection, Preservation and Transport System
Regulation Number: 21 CFR 866.2900
Regulation Name: Microbiological Specimen Collection and Transport System
Regulatory Class: Class I
Product Code: JTW
Dated: February 11, 2002
Received: February 12, 2002

Dear Mr. Stone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number:

Device Name: Sierra Diagnostics L.L.C. Urine Collection, Preservation and Transport System

Indications for Use:

The Sierra Diagnostics L.L.C. Urine Collection, Preservation and Transport System is indicated for use in the collection, preservation, and transportation of urine specimens at temperatures not exceeding 60°C for testing with the Abbott LCx® *Neisseria gonorrhoeae* and *Chlamydia trachomatis* assays.

PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IN NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Clinical Laboratory Devices

Over-The Counter Use _____

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